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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/085,390	02/28/2002	Michael Rothe	3648.034	6646

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Stephan A. Pendorf
PENDORF & CUTLIFF
5111 Memorial Highway
Tampa, FL 33634-7356

EXAMINER	
SNAY, JEFFREY R	

ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 09/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/085,390	ROTHE ET AL.	
	Examiner	Art Unit	
	Jeffrey R. Snay	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *12-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *03042003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of claims 1-11 in the reply filed on 07-08-05 is acknowledged. The traversal is on the ground(s) that examination of all claimed inventions in a single application would not impose a serious burden. This is not found persuasive because the search required for the nonelected apparatus would include numerous subclasses within class 422, including devices not restricted to the intended use of measuring a breath condensate. This expansive search is not required for the elected method.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 3-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, the specification fails to adequately depict or describe how the presently claimed invention would accomplish the steps of mixing the contents of different storage containers. It is noted that the sole figure in the application is of too poor quality and

insufficient detail to satisfy the enablement requirement. Claim 6 is further not enabled because the specification fails to identify any scope of meaning to the term "short lived biomolecules."

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, line 6, "the solutions" is indefinite because it lacks clear antecedent basis in the claim. Specifically, claim 1 at line 4 recites "a solution from a storage container." Thus, the plurality of solutions required later in the claim is ambiguous and misleading. Further in claim 1, line 9, the language "calibration or the at least one sensor" is incomprehensible.

Claim 6 is further indefinite because the specification fails to identify any scope of meaning to the term "short lived biomolecules."

Claim 10 is further indefinite because the language "making them and made available" is imcomprehensible, and the phrase "such as" renders the scope of the claim indefinite.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 2, 7, 8, 10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Gaston, IV et al ('368).

Gaston et al disclose a method for measuring parameters of a breath condensate, particularly nitrite and nitrate, which includes all of the presently recited steps. The disclosed method includes collecting a sample of breath condensate, delivering the collected sample to an analysis chamber of a sensor, and further delivering to the analysis chamber a reagent solution from a storage container. See particularly Gaston et al at column 5, lines 45-58. While Gaston et al teach the addition of solution for the purpose of acting as a reagent, it is noted that such addition would inherently also performed dilution of the sample. The combined sample and reagent mixture is analyzed and the measurement results transmitted for storage and display by an analysis unit (column 4, ultimate paragraph). Gaston et al further disclose, with respect to Figure 2A, that the reagent solution is discharged from a storage container (14) by a squeezing force externally imposed on a flexible wall (15). Temperature of the collected sample is regulated in the analysis chamber by means of a thermostically controlled heating coil (col. 5, lines 15-17). The device is further taught as being disposable (column 2, line 11).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 3-5 and 9 rejected under 35 U.S.C. 103(a) as being unpatentable over Gaston, IV et al in view of Besemer et al.

The method of Gaston et al, as descirbed above, differs from the instant claims in that it fails to further teach the steps of preliminary mixing of fluids in or from different storage containers. Gaston et al does however contemplate different reagent schemes, some of which involve mixing of different reagent components (see column 5, lines 35-44).

Besemer et al disclose a disposable cartridge for fluid analysis, which cartridge provides a plurality of fluid storage compartments and interconnecting means for enabling various mixing and sample dilution processes. It would have been obvious to one of ordinary skill in the art to supplement the method of Gaston et al with the additional ability to mix various reagents and diluents, as per the teaching of Besemer et al, in order to enhance the analytical capabilities and provide for additional measurement schemes.

12. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gaston, IV et al and Besemer et al as applied to claim 5 above, and further in view of Silkoff et al.

The method of Gaston et al, as modified in view of Besemer et al, fails to specify the provision of hydrogen peroxide or "short lived biomolecules". Gaston et al does contemplate a step of calibration (paragraph bridging columns 4 and 5). Additionally, Besemer et al makes obvious, for the reasons set forth in the previous paragraph, the

additional steps of mixing different reagent components, which would have been recognized by one of ordinary skill in the art as including calibration standards. Finally, Silkoff et al teach, in a method for conducting breath analysis, that hydrogen peroxide was known as an analyte of interest (column 1, 4th paragraph). As such, it would have been obvious to one of ordinary skill in the art to modify the method of Gaston et al to include a known concentration of hydrogen peroxide in at least one storage container in communication with the analysis chamber in order to facilitate calibration for subsequent sample measurement of hydrogen peroxide content.

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure as background information generally related to applicant's field of endeavor.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey R. Snay whose telephone number is (571) 272-1264. The examiner can normally be reached on Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jeffrey R. Snay
Primary Examiner
Art Unit 1743

jrs